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STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.

ATTORNEYS AT LAW

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\*LIMITED TO MATTERS  
AND PROCEEDINGS BEFORE  
FEDERAL COURTS & AGENCIES  
\*\*REGISTERED PATENT AGENT  
\*\*\*SENIOR COUNSEL

May 25, 2001

WRITER'S DIRECT NUMBER:  
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INTERNET ADDRESS:  
KVIDOVIC@SKGF.COM

Commissioner for Patents  
Washington, D.C. 20231

RECEIVED

MAY 29 2001

TECH CENTER 1600/2900

Re:   U.S. Utility Patent Application  
Appl. No. 09/809,060; Filed: March 16, 2001

For:   A Method for Generating Immunogens that Elicit Neutralizing  
Antibodies Against Fusion-Active Regions of HIV Envelope Proteins

Inventors:   Wild *et al.*

Our Ref:   1900.0260001/JMC/KKV

Sir:

Transmitted herewith for appropriate action are the following documents:

1.   Information Disclosure Statement (*in duplicate*);
2.   Form PTO-1449 (12 sheets citing 49 documents);
3.   49 documents cited in Form PTO-1449 attached; and
4.   One (1) return postcard.

It is respectfully requested that the attached postcard be stamped with the date of filing of these documents, and that it be returned to our courier. In the event that extensions of time are necessary to prevent abandonment of this patent application, then such extensions of time are hereby petitioned.

STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.

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Commissioner for Patents  
May 25, 2001  
Page 2

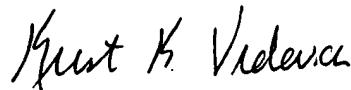
MAY 29 2001

TECH CENTER 1600/2300

The U.S. Patent and Trademark Office is hereby authorized to charge any fee deficiency, or credit any overpayment, to our Deposit Account No. 19-0036. A duplicate copy of this letter is enclosed.

Respectfully submitted,

STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.



Kristin K. Vidovich  
Attorney for Applicants  
Registration No. 41,448

JMC/KKV/lam

Enclosures

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE



In re application of:

WILD *et al.*

Appl. No. 09/809,060

Filed: March 16, 2001

For: **A Method for Generating  
Immunogens that Elicit  
Neutralizing Antibodies Against  
Fusion-Active Regions of HIV  
Envelope Proteins**

Confirmation No.

Art Unit: *To be assigned*

Examiner: *To be assigned*

Atty. Docket: 1900.0260001/JMC/KKV

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**Information Disclosure Statement**

Commissioner for Patents  
Washington, D.C. 20231

Sir:

Listed on accompanying Form PTO-1449 are documents that may be considered material to the examination of this application, in compliance with the duty of disclosure requirements of 37 C.F.R. §§ 1.56, 1.97 and 1.98. A copy of each document is provided.

The Examiner's attention is directed to co-pending U.S. Patent Application Nos.

09/480,336, filed January 7, 2000, and

09/779,451, filed February 9, 2001,

which are directed to related technical subject matter. The identification of these U.S. Patent Applications is not to be construed as a waiver of secrecy as to that application now or upon issuance of the present application as a patent. The Examiner is respectfully requested to consider the cited applications and the art cited therein during examination.

In accordance with 37 C.F.R. § 1.98(A)(3), Applicants' undersigned representative submits the following concise explanation of the relevance of the non-English language document, Document No. AM2 cited on Form PTO-1449.

Document No. AM2, Patent No. WO 92/19742, is in the French language with an English language abstract. The relevance of Document No. AM2 can be ascertained by reference to the English language abstract appearing thereon.

Where the publication date of a listed document does not provide a month of publication, the year of publication of the listed document is sufficiently earlier than the effective U.S. filing date and any foreign priority date so that the month of publication is not in issue. Applicants have listed publication dates on the attached PTO-1449 based on information presently available to the undersigned. However, the listed publication dates should not be construed as an admission that the information was actually published on the date indicated.

Applicants reserve the right to establish the patentability of the claimed invention over any of the information provided herewith, and/or to prove that this information may not be prior art, and/or to prove that this information may not be enabling for the teachings purportedly offered.

This statement should not be construed as a representation that a search has been made, or that information more material to the examination of the present patent application does not exist. The Examiner is specifically requested not to rely solely on the material submitted herewith.

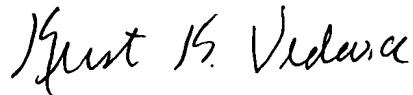
This Information Disclosure Statement is being filed before the mailing date of a first Office Action on the merits. No statement or fee is required.

It is respectfully requested that the Examiner initial and return a copy of the enclosed PTO-1449, and indicate in the official file wrapper of this patent application that the documents have been considered.

The U.S. Patent and Trademark Office is hereby authorized to charge any fee deficiency, or credit any overpayment, to our Deposit Account No. 19-0036. A duplicate copy of this pleading is enclosed.

Respectfully submitted,

STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.



Kristin K. Vidovich  
Attorney for Applicants  
Registration No. 41,448

Date: May 25, 2001

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FORM PTO-1449 <u>INFORMATION DISCLOSURE STATEMENT</u>		ATTY. DOCKET NO. 1900.0260001	APPLICATION NO. 09/809,060
		APPLICANT WILD et al.	
		FILING DATE March 16, 2001	GROUP To be assigned

## U.S. PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB-CLASS	FILING DATE
	AA1	5,464,933	11/07/1995	Bolognesi et al.	530	324	06/07/1993
	AB1	5,656,480	08/12/1997	Wild et al.	435	325	01/27/1995
	AC1	5,444,044	08/22/1995	Jiang et al.	514	12	03/26/1992
	AD1	5,840,843	11/24/1998	Jiang et al.	530	350	06/07/1995
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## FOREIGN PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB-CLASS	TRANSLATION
	AL1	WO 94/02505	02/03/1994	WIPO			Yes No
	AM1	WO 94/28920	12/22/1994	WIPO			Yes No
	AN1	WO 96/19495	06/27/1996	WIPO			Yes No
	AO1	WO 96/40191	12/19/1996	WIPO			Yes No
	AP1	WO 88/08429	11/03/1988	WIPO			Yes No

## OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

AR	1	Alkhatib, G., et al., "CC CKR5: A RANTES, MIP-1 $\alpha$ , MIP-1 $\beta$ Receptor as a Fusion Cofactor for Macrophage-Tropic HIV-1," <i>Science</i> 272:1955-1958, Association for the Advancement of Science (June 1996).
AS	1	Allan, J.S., et al., "Strong Association of Simian Immunodeficiency Virus (SIVagm) Envelope Glycoprotein Heterodimers: Possible Role in Receptor-Mediated Activation," <i>AIDS Res. Hum. Retroviruses</i> 8:2011-2020, Mary Ann Leibert, Inc., Publishers (December 1992).
AT	1	Bosch, M.L., et al., "Identification of the Fusion Peptide of Primate Immunodeficiency Viruses," <i>Science</i> 244:694-697, Association for the Advancement of Science (May 1989).

EXAMINER	DATE CONSIDERED
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## FOREIGN PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB-CLASS	TRANSLATION
	AL2	WO 91/09872	07/11/1991	WIPO			Yes No
	AM2	WO 92/19742	11/12/1992	WIPO			Abstract Yes No
	AN2	WO 95/21912	08/17/1995	WIPO			Yes No
	AO2	WO 96/12023	04/25/1996	WIPO			Yes No
	AP2	WO 00/06599	02/10/2000	WIPO			Yes No

## OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

AR	2	Broder, C.C., and Dimitrov, D.S., "HIV and the 7-Transmembrane Domain Receptors," <i>Pathobiol.</i> 64:171-179, S. Karger AG (1996).
AS	2	Chan, D.C., et al., "Core Structure of gp41 from the HIV Envelope Glycoprotein," <i>Cell</i> 89:263-273, Cell Press (April 1997).
AT	2	Chan, D.C., and Kim, P.S., "HIV Entry and Its Inhibition," <i>Cell</i> 93:681-684, Cell Press (May 1998).

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	AN						Yes No
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	AP						Yes No

## OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

AR	3	Chen, S.S.-L., et al., "Mutational Analysis of the Leucine Zipper-Like Motif of the Human Immunodeficiency Virus Type 1 Envelope Transmembrane Glycoprotein," J. Virol. 67:3615-3619, American Society for Microbiology (June 1993).
AS	3	Chen, S.S.-L., "Functional Role of the Zipper Motif Region of Human Immunodeficiency Virus Type 1 Transmembrane Protein gp41," J. Virol. 68:2002-2010, American Society for Microbiology (March 1994).
AT	3	Chen, S.S.-L., et al., "Mutations in the Leucine-Like Heptad Repeat Sequence of Human Immunodeficiency Virus Type 1 gp41 Dominantly Interfere with Wild-Type Virus Infectivity, J. Virol. 72:4765-4774, American Society for Microbiology (June 1998).

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	AN						Yes No
	AO						Yes No
	AP						Yes No

## OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

AR	4	Choe, H., et al., "The $\beta$ -Chemokine Receptors CCR3 and CCR5 Facilitate Infection by Primary HIV-1 Isolates," Cell 85:1135-1148, Cell Press (June 1996).
AS	4	Clapham, P.R., et al., "Human Immunodeficiency Virus Type 2 Infection and Fusion of CD4-Negative Human Cell Lines: Induction and Enhancement by Soluble CD4," J. Virol. 66:3531-3537, American Society for Microbiology (June 1992).
AT	4	Dalgleish, A.G., et al., "The CD4 (T4) antigen is an essential component of the receptor for the AIDS retrovirus," Nature 312:763-767, Macmillan Publishers Ltd. (December 1984).

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	AO						Yes No
	AP						Yes No

## OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

AR	5	Delwart, E.L., et al., "Retroviral Envelope Glycoproteins Contain a 'Leucine Zipper'-like Repeat," AIDS Res. Hum. Retroviruses 6:703-706, Mary Ann Leibert, Inc., Publishers (June 1990).				
AS	5	Deng, H., et al., "Identification of a major co-receptor for primary isolates of HIV-1," Nature 381:661-666, Macmillan Publishers Ltd. (June 1996).				
AT	5	Dimitrov, D.S., "Fusin - a place for HIV-1 and T4 cells to meet," Nat. Med. 2:640-641, Nature Publishing Company (June 1996).				

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MAY 25 2001

Page 6 of 12

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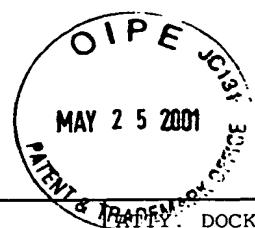
## OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

AR	6	Doranz, B.J., et al., "A Dual-Tropic Primary HIV-1 Isolate That Uses Fusin and the $\beta$ -Chemokine Receptors CKR-5, CKR-3, and CKR-2b as Fusion Cofactors," Cell 85:1149-1158, Cell Press (June 1996).
AS	6	Dragic, T., et al., "HIV-1 entry into CD4 $^{+}$ cells is mediated by the chemokine receptor CC-CKR-5," Nature 381:667-673, Macmillan Publishers Ltd. (June 1996).
AT	6	Eiden, L.E., and Lifson, J.D., "HIV interactions with CD4: a continuum of conformations and consequences," Immunol. Today 13:201-206, Elsevier Science Publishers Ltd. (1992).

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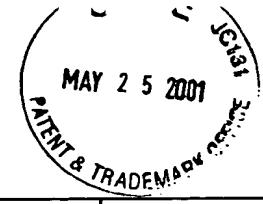
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	AL						Yes No
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## OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

AR	7	Feng, Y., et al., "HIV-1 Entry Cofactor: Functional cDNA Cloning of a Seven-Transmembrane, G Protein-Coupled Receptor," <i>Science</i> 272:872-877, Association for the Advancement of Science (May 1996).
AS	7	Freed, E.O., et al., "Characterization of the fusion domain of the human immunodeficiency virus type 1 envelope glycoprotein gp41," <i>Proc. Natl. Acad. Sci. USA</i> 87:4650-4654, National Academy of Sciences of the USA (June 1990).
AT	7	Furata, R.A., et al., "Capture of an early fusion-active conformation of HIV-1 gp41," <i>Nat. Struct. Biol.</i> 5:276-279, Nature Publishing Company (April 1998).

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	AN						Yes No
	AO						Yes No
	AP						Yes No

## OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

AR	<u>8</u>	Gallaher, W.R., et al., "A General Model for the Transmembrane Proteins of HIV and Other Retroviruses," AIDS Res. Hum. Retroviruses 5:431-440, Mary Ann Leibert, Inc., Publishers (August 1989).
AS	<u>8</u>	Lifson, J.D., et al., "Induction of CD4-dependent cell fusion by the HTLV-III/LAV envelope glycoprotein," Nature 323:725-728, Macmillan Publishers Ltd. (October 1986).
AT	<u>8</u>	Lifson, J.D., et al., "AIDS Retrovirus Induced Cytopathology: Giant Cell Formation and Involvement of CD4 Antigen," Science 232:1123-1127, Association for the Advancement of Science (May 1986).

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## OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

AR	9	McDougal, J.S., et al., "Binding of HTLV-III/LAV to T4 <sup>+</sup> T Cells by a Complex of the 110K Viral Protein and the T4 Molecule," <i>Science</i> 231:382-385, Association for the Advancement of Science (January 1986).
AS	9	Salzwedel, K., et al., "A Conserved Tryptophan-Rich Motif in the Membrane-Proximal Region of the Human Immunodeficiency Virus Type 1 gp41 Ectodomain Is Important for Env-Mediated Fusion and Virus Infectivity," <i>J. Virol.</i> 73:2469-2480, American Society for Microbiology (March 1999).
AT	9	Sattentau, Q.J. and Moore, J.P., "Conformational Changes Induced in the Human Immunodeficiency Virus Envelope Glycoprotein by Soluble CD4 Binding," <i>J. Exp. Med.</i> 174:407-415, The Rockefeller University Press (August 1991).

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	AP						Yes No

## OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

AR	<u>10</u>	Slepushkin, V.A., et al., "Investigation of Human Immunodeficiency Virus Fusion Peptides. Analysis of Interrelations Between Their Structure and Function," AIDS Res. Hum. Retroviruses 8:9-18, Mary Ann Leibert, Inc., Publishers (January 1992).
AS	<u>10</u>	Weissenhorn, W., et al., "Atomic structure of the ectodomain from HIV-1 gp41," Nature 387:426-430, Macmillan Publishers Ltd. (May 1997).
AT	<u>10</u>	Wild, C., et al., "A synthetic peptide inhibitor of human immunodeficiency virus replication: Correlation between solution structure and viral inhibition," Proc. Natl. Acad. Sci. USA 89:10537-10541, National Academy of Sciences of the USA (November 1992).

EXAMINER

DATE CONSIDERED

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.



FORM PTO-1449  <u>INFORMATION DISCLOSURE STATEMENT</u>		DOCKET NO. 1900.0260001		APPLICATION NO. 09/809,060	
		APPLICANT WILD et al.			
		FILING DATE March 16, 2001		GROUP To be assigned	

## U. S. PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB-CLASS	FILING DATE
	AA						
	AB						
	AC						
	AD						
	AE						
	AF						
	AG						
	AH						
	AI						
	AJ						
	AK						

## FOREIGN PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB-CLASS	TRANSLATION
	AL						Yes No
	AM						Yes No
	AN						Yes No
	AO						Yes No
	AP						Yes No

## OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

	AR	<u>11</u>	Wild, C.T., et al., "Peptides corresponding to a predictive $\alpha$ -helical domain of human immunodeficiency virus type 1 gp41 are potent inhibitors of virus infection," Proc. Natl. Acad. Sci. USA 91:9770-9774, National Academy of Sciences of the USA (October 1994).
	AS	<u>11</u>	Wild, C., et al., "Propensity for a leucine zipper-like domain of human immunodeficiency virus type 1 gp41 to form oligomers correlates with a role in virus-induced fusion rather than assembly of the glycoprotein complex," Proc. Natl. Acad. Sci. USA 91:12676-12680, National Academy of Sciences of the USA (December 1994).
	AT	<u>11</u>	Xu, J-Y., et al., "Epitope Mapping of Two Immunodominant Domains of gp41, the Transmembrane Protein of Human Immunodeficiency Virus Type 1, Using Ten Human Monoclonal Antibodies," J. Virol. 65:4832-4838, American Society for Microbiology (September 1991).

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	AN						Yes No
	AO						Yes No
	AP						Yes No

## OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

AR	<u>12</u>	Co-pending U.S. Patent Application No. 09/480,336.				
AS	<u>12</u>	Co-pending U.S. Patent Application No. 09/779,451.				
AT						

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